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EXAMINER	
MCKELVEY, TERRY ALAN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/734,329	DE CROMBRUGGHE ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,9,11-15,17-30 and 48-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48-55* is/are allowed.

6)☒ Claim(s) *1,3,6,9,11-15 and 17-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

GP

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

Claim Rejections - 35 USC § 112

Claims 1, 3, 6, 9, 12-15, and 18-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record set forth in the paper mailed 10/2/03. Applicants' arguments filed 1/6/04 have been fully considered but they are not deemed to be persuasive.

The claims are drawn to a DNA segment comprising a protein coding region encoding an Osterix polypeptide. The claims are genus claims because they DNA segments drawn to encoding a polypeptide that is a genus: Osterix (polypeptide comprising SEQ

ID NO:2), Osterix isoforms, and other members of the Osterix family. The genus members are vague and indefinite for the reasons set forth below. It is unclear what, if any, structure or function define the genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is that some claims have a partial sequence drawn to a part of SEQ ID NO:2, but not the entire SEQ ID NO:2 sequence. (The claims drawn to the DNA segments comprising a protein coding region encoding an Osterix polypeptide which encode the entire SEQ ID NO:2 are not a part of the instant rejection.) The partial structures given in some of the claims is not a description of the actual, entire structure of the Osterix polypeptide. The other claims lack even the partial structure. The specification describes the entire structure of two Osterix polypeptides, the mouse Osterix sequence (SEQ ID NO:2) and the human sequence (shown in Figure

10 of the Set A figures). There is no description of the specific structure that defines the genus as claimed and there is no description of what parts of the amino acid sequence can be varied or must be retained. Note: the sequence comparison in Figure 10 merely shows what amino acids are conserved between the single mouse sequence and single human sequence for the protein. It does not describe what sequences are essential for function or what sequences can be varied. It is also not a description of the genus "Osterix polypeptide".

Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompasses Osterix polypeptide.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of

Osterix polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the DNA segment encoding an Osterix polypeptide comprising SEQ ID NO:2, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Response to Arguments

The applicant argues that the claims provide a structural description of the features of an Osterix polypeptide and

further embellish this with partial sequences in certain dependent claims. This argument is not persuasive because the claims merely recite what very general domains the Osterix polypeptide encoded by the claimed DNA segment comprises, not the complete structure of the Osterix polypeptide itself, not even in terms of a general complete structure. As discussed in the rejection below, it is unclear what constitutes an Osterix polypeptide as claimed, so the complete structure of the genus of Osterix polypeptide is unclear and not described. Additionally, the very general domains claimed as a part of the Osterix polypeptide are hardly even distinguishing characteristics because each of the transactivation, zinc finger, and proline rich domains are general motifs that are present in the form of different specific sequences in literally hundreds or thousands of different proteins in the art. They are not interchangeable domains because the specific sequence of each example of the domains may confer a different function. For example, one zinc finger domain usually cannot functionally substitute for another zinc finger domain because the different sequences of the different zinc finger domains confers binding to different nucleic acid sequences. So, by claiming (a DNA segment encoding) an Osterix polypeptide comprising a transactivation domain, a zinc finger domain, and a proline rich

domain, the claim actually encompasses (a DNA segment encoding) any Osterix polypeptide (whatever that means) that has any transactivation domain, zinc finger domain, and proline rich domain, not just the particular domains from an Osterix polypeptide. Many transactivation domains, zinc finger domains, and proline rich domains are known in the art; they are not the part of the claims that lack written description. It is the Osterix polypeptide part of the claims that lack written description. The dependent claims that recite some sequence limitations merely define a part of the polypeptide (one domain), but the rest of the polypeptide is left undefined and thus the (DNA segment encoding) the polypeptide for those claims still have not been described because a description of the genus of the whole polypeptide (and thus DNA segment encoding the polypeptide) is needed in order to meet the requirements of 35 USC 112, first paragraph.

The applicant argues that specific examples from two animals are provided and structural features are included in the claims. This argument is not persuasive in overcoming the instant rejection essentially for the reasons described above. The two examples of Osterix polypeptide does not describe the genus, especially isoforms and other members of the Osterix family, more especially because it is not even clear what is

encompassed by "Osterix polypeptides". For example, what is the description of Osterix polypeptide from a cat? What is a description of the different isoforms of Osterix polypeptide from a cat? The claimed structural features are so general that they are not limited to those domains from an Osterix polypeptide, but read on any of those domains from any source, including totally unrelated proteins that have any of those domains. There is no information concerning which parts of the sequence which are required for function and thus would be expected to be retained in all genus members. Therefore, in light of all of the available evidence, including the rejections set forth above and in the previous Office Action, the applicant's arguments and the arguments set forth above, the claims continue to fail to comply with the written description requirement and thus the rejection of the claims under 35 USC 112, first paragraph is properly maintained.

Claims 1, 3, 6, 9, 11-15, and 17-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record set forth in the paper mailed

10/2/03. Applicants' arguments filed 1/6/04 have been fully considered but they are not deemed to be persuasive.

Regarding claim 1, etc, the use of "Osterix polypeptide" renders the claims vague and indefinite because the metes and bounds of what constitutes such a polypeptide is unclear. "Osterix" appears to be a term coined by the applicants and thus the specification is the only source of the definition of this term. At the top of page 18 of the specification, the following is recited: "The inventors have characterized this molecule as comprising, 428 amino acids, as defined in SEQ ID NO:2. ... Due to the specification of the gene's expression in osteoblasts and in osteoblast precursor cells, the inventors have labeled the identified 428 amino acid molecule "Osterix"." However, later on that page the following is recited: "As used hereinbelow, the term Osterix should be interpreted to include not only the full length molecule but also isoforms, ... and other members of the Osterix family." Thus, reading the claims and specification as broadly as is reasonable, the second definition seems to be intended. However, because the metes and bounds of what constitutes isoforms and other members of the Osterix family are unclear (because they are not clearly defined), then the term "Osterix" renders the claims vague and indefinite.

Response to Arguments

The applicant argues that it is black letter law that applicants are permitted to be their own lexicographer and that no claim merely recites "Osterix polypeptide". These arguments are not persuasive because of course the applicant can be their own lexicographer; that was not questioned in the rejection. But, if the applicant is going to be their own lexicographer, then the definition of their coined terms must not be indefinite, or the claims having those terms are properly rejected under 35 USC 112, second paragraph. It does not matter that no claim merely recites "Osterix polypeptide"; claims seldom have only the coined term. The use of the term in the claims is part of what defines the claims and thus since the term is made unclear by the definition of the term in the specification, it makes that part of the claims indefinite. Making any part of a claim indefinite makes the whole claim vague and indefinite because the metes and bounds of what is encompassed by the claims is rendered unclear. The recitation of the domains does not define Osterix polypeptide, but merely indicate what domains are comprised by the polypeptide. Does the applicant imply that Osterix polypeptide is any polypeptide that comprises a transactivation domain, zinc finger domain, and a proline rich domain? If so, then this definition is not

supported by the specification. Additionally, there are many other very unrelated proteins having those domains in the art which based upon the other recited definitions of Osterix polypeptide do not appear to be Osterix polypeptides. The provision of specific sequences for Osterix polypeptides does not further clarify the definition of Osterix polypeptides, unless the applicant intends to limit the definition of Osterix polypeptide to consist of one of those two specific, complete sequences, which does not appear to be the case. Again, the specification most broadly defines Osterix (polypeptide) as: "As used hereinbelow, the term Osterix should be interpreted to include not only the full length molecule but also isoforms, ... and other members of the Osterix family." However, because the metes and bounds of what constitutes isoforms and other members of the Osterix family are unclear (because they are not clearly defined), then the term "Osterix" renders the claims vague and indefinite. Additionally, the lack of the applicant providing a clear definition of what constitutes Osterix isoforms and other members of the Osterix family makes the applicant's arguments not persuasive in overcoming the instant rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the

scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Terry A. McKelvey

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

October 15, 2005